

Appl. No.: 10/009,453  
Response dated August 12, 2005  
Reply to Office Action of May 16, 2005

### **Remarks**

Claims 9, 10, 12-16 and 18-24 are pending in this application.

Before discussing the rejections over the prior art, Applicants deem it prudent to set forth what they consider to be their invention. The broadest claim, claim 9 is directed to a composition comprising:

- (a) an active ingredient selected from a group consisting of a cosmetically-active ingredient, a pharmaceutically-active ingredient, and mixtures thereof; and
- (b) metal soap nanoparticles having a mean diameter of from about 10 to 300 nanometers wherein the metal soap nanoparticles are coated with a coating compound selected from the group consisting of a protective colloid, an emulsifier, and mixtures thereof.

Claims 12, 13, and 14 are directed to compositions containing from 0.1 to 5% by weight of the metal soap nanoparticles, 0.5 to 3% by weight of the nanoparticles and 1 to 2% by weight of the soap nanoparticles.

Claim 15 is directed to a process for enhancing the stability, opacity and consistency of a cosmetic or pharmaceutical composition. The process comprises metal soap nanoparticles having a mean diameter of from about 10 to 300 nm to the composition. The metal soap nanoparticles being coated with the compound selected from the group consisting of a protective colloid, an emulsifier and mixtures thereof.

The remaining claims are directed to processes and compositions containing particular amounts of coating compound on the nanoparticles.

Claims 9-10, 15-16, and 21-24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Selvaraj et al. (WO 97/13503). Applicants respectfully submit that Selvaraj et al. neither teaches nor suggests the present invention.

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It is clear under patent law, that a rejection under 35 U.S.C. 102(b) must be based on a single reference which discloses each and every limitation in the claims. Applicants submit that Selvaraj is efficient in neither teaching nor suggesting metal soap nanoparticles coated with a compound selected from the group consisting of protective colloids, emulsifiers and mixtures thereof, and neither teaches nor suggests introducing the coated metal soap nanoparticles into a cosmetic or pharmaceutical composition to enhance the stability, opacity and consistency of the composition.

Selvaraj et al. discloses a method for making nanoparticles of therapeutic and diagnostic agents, cosmetic, diet, photographic, food, pesticides agent and the like (see abstract). In particular, Selvaraj et al. relates to the field of drug manufacture, and, in particular, to the synthesis of therapeutic, diagnostic, analgesic, and anti-inflammatory compositions having a medium particle size less than about 5,000 nm.

Applicants submit that a composition having a median particle size of 5,000 nm would not be considered a nanoparticle composition by anyone skilled in the art. Selvaraj et al. have defined their material as having a median particle size of less than 5 microns. Clearly, one skilled in the art would not consider a composition with a median particle size of 5 microns to be a nanoparticle mixture. First, there is no upper limit to the particle size, only that one-half of the particles can have a particle size greater than 5 microns. The composition prepared by Selvaraj et al. need not contain any particles with a particle size in the nanometer range.

Selvaraj et al. discloses a process for making the drugs in the particular particle size range whether it be considered nanoparticles or merely small particles. The process comprises forming a solution of the therapeutic or diagnostic compound in a solvent. Introducing a matrix material into the solution of the therapeutic or diagnostic material to form a composite mixture; spray drying the composite mixture to form a nanocomposite in which the nanoparticles are distributed throughout the matrix material forming the nanocomposite and dissolving the matrix material from the nanocomposite to form the nanoparticles. Applicants invite the Examiner's attention to the description

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at pages 1 through 25 and, in particular, the examples beginning with example 2. The example 2 at page 27 beginning at line 13, Selvaraj et al. teach that :

"the spray dried nanocomposite powders were dispersed in water with surfactant by sonication using an ultrasonic power supply having a frequency of either 20 or 80 kHz for about 1 to about 5 min. From particle size analysis, it was determined that these nanocomposite powders, when rehydrated in water with 0.1% (w/v) Pluronic™ F-68 surfactant, yielded ethyl 3,5-diacetamido-2,4,6-triiodobenzoate nanoparticle formulations with median particle diameter of 160 to 275 nm. "

Table 1 discloses the particle size of active material after the matrix material has been separated from the nanoparticles of the active material.

All of the examples utilize the same process and recover nanoparticles of the active material in a same or similar manner by dissolving away the matrix material.

The surface-treating agents included in the nanocomposite particle is intended to provide a uniform dispersion of the nanoparticles of the active ingredients in the carrier after dissolution of the matrix material.

In reading Selvaraj et al., one must be careful to separate the various materials in relation to the nomenclature. As set forth at page 4, lines 22-25, definitions of the term "composite mixture," "nanocomposite," and "matrix material" are set forth. The term "nanoparticles" is defined at page 6, lines 1 and 2.

A comparison of the present invention with the teachings of Selvaraj et al. clearly indicates that there is no relation between the nanoparticles disclosed in Selvaraj and the nanoparticles of the present invention.

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**Comparison Table**

|                                   | <u>Selvarai et al.</u>  | <u>Present Invention</u>   |
|-----------------------------------|---|--|
| Nano Particles                    | Active agent only, particle size median particle size less than 5,000 nm                                      | Coated metal soap (no active agent)<br>10-300 nm median particle size                                |
| Nanocomposite                     | Nanoparticles embedded in a matrix. Nanocomposite must be of a particle size larger than nanoparticles.       | No nanocomposite; no nanoparticles embedded in larger particles.                                     |
| Surface-treating agent            | Dispersed throughout nanocomposite or added when matrix is being dissolved from nanocomposite (see examples). | Coated on surface of metal soap particles.   |
| Purpose of surface-treating agent | To make active agent dispersible in a carrier (see examples).   | To prevent the metal soap nanoparticles from agglomerating and to be dispersible in the composition. |
| Active ingredient                 | Dispersed in matrix of nanocomposite particles and recovered when matrix material is dissolved away.          | No active ingredient only coated metal soap particles.   |

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The above table clearly shows that the nanoparticles of Selvaraj et al. bear no relation to the nanoparticles of the present invention, the composition of the present invention or the method of the present invention.

Claim 9 is directed to a composition. The composition comprises

- (a) an active ingredients and
- (b) metal soap nanoparticles having a mean diameter of from about 10 to 300 nm, wherein the metal soap nanoparticles are coated with a coating compound selected from the group consisting of a protective colloid, an emulsifier, and mixtures thereof.

It is clear that Selvaraj et al. do not make any composition containing an active ingredient and metal soap nanoparticles coated as in the present invention. Selvaraj et al. disclose nanocomposite particles which comprise nanoparticles of the active ingredient embedded in a matrix material which optionally can contain an emulsifier, surfactant and the like. However, the materials are not coated on the surface of the nanocomposite particles.

The nanocomposite particles disclosed in Selvaraj comprise interim particles which are immersed in a solvent for the matrix material to recover the nanoparticles of the invention. The nanoparticles of the invention which are the active ingredient, can then be incorporated into various therapeutic diagnostic materials and the like. Applicants submit that there is neither teaching nor suggestion in Selvaraj et al. that the nanocomposite particles comprising the nanoparticles of the active ingredient and a matrix material be coated with a protective colloid or emulsifier and the like.

Selvaraj et al. does not teach or suggest any utility for the nanocomposite particles except for the recovery of the nanoparticles of the active ingredient. That is, the nanocomposite particles are introduced into a solvent for the matrix material, the matrix material dissolved from the nanocomposite particles to free the nanoparticles of the active principle.

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The coated nanoparticles of the present invention are not related in any way to the nanoparticles disclosed in Selvaraj et al. or the nanocomposite particles. Selvaraj et al. at page 5, line 23 and 24, discloses that the nanoparticles have a median size that at least about 5,000 nm (5 microns). To accommodate nanoparticles in this particle size range, the nanocomposite particle disclosed in Selvaraj et al. must have a particle size much larger than less than 5,000 nm. The nanocomposite particles disclosed Selvaraj et al., if they are to contain multiple nanoparticles of the active ingredient which can have a median particle size range of less than 5,000 nm, must have a particle size much larger than the multiple particles of the active ingredient which are embedded in the nanocomposite particles.

Selvaraj et al. does not disclose mixing the nanocomposite particles with an active ingredient selected from the group consisting of cosmetically-active ingredients, a pharmaceutically-active ingredient and mixtures thereof. Selvaraj et al. only discloses mixing the nanocomposite particles with a solvent for the matrix material to free the nanoparticle in the composition.

Applicants submit that the deficiencies in the teachings of Selvaraj et al. makes a rejection under 35 U.S.C. 102(b) of the present invention untenable. Applicants submit that Selvaraj et al. neither teaches nor suggests any of the limitations in the claims presently in the application. Clearly, Selvaraj et al. does not disclose mixing the nanocomposite particles with an active ingredient selected from the group as set forth in the application. In addition, Selvaraj et al. neither teaches nor suggests coating the nanocomposite particles with a protective colloid or an emulsifier. Further, Selvaraj et al. neither teaches a metal soap nanoparticle.

Although Selvaraj et al. discloses various parameters in the specification, the parameters basically refer to the nanoparticles and not the nanocomposite particles produced by the spray-drying process. Selvaraj et al. does not disclose any utility for the nanocomposite particles except as a means for forming the nanoparticles and does not disclose the addition of the nanocomposite particles to any composition in which the

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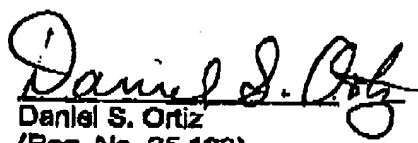
nanocomposite particles maintain their integrity. Applicants again invite the Examiner's attention to all of the examples which disclose that the nanocomposite particles are introduced into a solvent for the matrix material and the nanoparticles are recovered after the matrix material has been dissolved away from the nanoparticles.

Applicants submit that Selvaraj et al. does not provide a basis for a rejection under 35 U.S.C. 102(b) or any suggestion to one skilled in the art to form nanoparticles of a metal soap for inclusion in a composition to enhance the stability, opacity and consistency of a cosmetic or pharmaceutical composition.

Applicants request that the Examiner, when reviewing the teachings of Selvaraj et al. consider the differences between the nanoparticles and the nanocomposite particle disclosed in the reference. Applicants submit that there is no useful composition in which the nanocomposite particles are included. As set forth above, the nanocomposite particles are utilized only as a carrier for the nanoparticles (active components) and are dissolved away from the nanoparticles before the nanoparticles are included in a useful composition.

Applicants submit that in view of the above discussion, it is clear that a rejection under 35 U.S.C. 102(b) over Selvaraj et al. is untenable and respectfully request that the rejection be reconsidered and withdrawn.

Respectfully submitted,

  
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